

REMARKS

Reconsideration and continued examination of the above-identified application respectfully requested.

The amendments to the claims do not substantively change the scope of the claims but simply are editorial in nature and/or further define what the applicants regard as the invention. The amendments are fully supported by the present application, including the claims as originally filed. Accordingly, no questions of new matter should arise and entry of this amendment is respectfully requested.

If the Examiner recalls, the undersigned contacted the Examiner to arrange an interview, but unfortunately the Examiner was proceeding with the issuance of a final Office Action. However, the Examiner promised that he would consider this evidence submitted by way of Declaration as well as the arguments set forth below. Furthermore, the Examiner did agree that if an interview was requested, an interview with the Examiner would be granted and that the arguments set forth below as well as the amendments would be considered and entered.

At page 2 of the final Office Action, the Examiner rejects claims 1-12, 14-19, 23, and 24 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Examiner essentially relies on the reasons set forth in the first Office Action. The Examiner asserts that the word "substantially" is indefinite. More specifically, the Examiner states that the applicants at page 2, line 33, assert that 2-5% water permits stability while on page 3, line 1, the applicants assert that 15% water is substantially no water in terms of stability. The Examiner further asserts that "organic solvents" are also undefined since vegetable oil is an organic solvent. For the following reasons, this rejection is respectfully traversed.

Insofar as the Examiner's remark regarding the word "substantially," or "substantially no water," according to M.P.E.P. §2173.05(c), the term "substantially" is definite when used in conjunction with another term to describe a particular characteristic of the claimed invention (e.g. substantially no water). Furthermore, applicants' remark about U.S. Patent No. 4,946,681, which reports greater stability for azadirachtin in solutions of aprotic solvents containing less than 2-5% water (page 2, lines 32-33) and about U.S. Patent No. 5,001,146, which indicates decreasing the water content to less than 15% by volume (page 3, line 1), are not examples of what is

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considered “substantially no water” for purposes of the present invention. These two patents are offered for background purposes and nowhere in the present application is there any mention that these particular percentages referenced by the Examiner are a definition of what is meant by “substantially no water” for purposes of the present application. Clearly, at the bottom of page 5 of the present application, examples of substantially no water are provided and preferably this amount includes less than about 2% by weight and even more preferably less than 1% by weight of water, based on the weight of the concentrate or formulation.

With respect to the term “organic solvent,” the meaning of this term is clear to one having ordinary skill in the relevant art, especially in light of the portions of the specification quoted. An organic solvent does not include vegetable oil. To one of ordinary skill in the art, an organic solvent could be ethanol, xylene, and other organic solvents. Thus, the term “organic solvent” is a term widely recognized by those skilled in the art. For instance, Hawley’s Condensed Chemical Dictionary (14th Ed.) (2001) clearly recognizes the term “organic solvent” and shows groups that include esters, ethers, ketones, amines, nitrified and chlorinated hydrocarbons, and the like. Clearly, this is quite different from a vegetable oil. In fact, the same Hawley’s Condensed Chemical Dictionary defines vegetable oil in a manner that clearly would not be an organic solvent. Thus, the Examiner’s position with respect to the term “organic solvents” is not supported by any record and clear evidence has been submitted by the applicants to show that the Examiner’s position is not accurate.

With respect to the Examiner’s reliance on Butler ’097, the Examiner relies on this patent to further support the §112 rejection. The Examiner asserts that Butler et al. shows a storage stable azadirachtin that describes storage stability differently from the present application. However, the Examiner’s position still does not alter the fact that storage stability has been properly and fully described in the present application. As appreciated by the Examiner, storage stable is clearly described at page 7, lines 24-30. Thus, an example of storage stable has been provided by the applicants in the present application. In view of the above, the rejection under 35 U.S.C. §112, second paragraph should be withdrawn.

The claimed invention, in part, is a pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin or a neem seed extract, wherein said formulation is preferably storage stable and contains substantially no water. The formulation of the present invention can be diluted with water or other medium at the site of use. The present

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invention provides a way to maintain a storage stable product that is easily useable when needed. The formulation of Butler et al. differs on the ground that Butler et al. does not show a formulation with substantially no water. The lack of water is an important feature of the claimed invention, since the presence of water is known to degrade azadirachtin, as is set forth at page 5, lines 19-23 of the application. Degradation of azadirachtin due to water is also explained in enclosed excerpt from the Pesticide Research Journal, dated 1999. Moreover, the attached Declaration from one of the inventors, namely, Dr. M.C. Gopinathan, shows that in the pesticide composition of the present invention, azadirachtin in sesame oil, remains stable compared to azadirachtin containing water. This indicates that vegetable oil, like sesame oil, provides stability to azadirachtin in neem seed extracts, and if water is present in the composition, it causes rapid degradation to azadirachtin.

Furthermore, the examples in Butler et al. use organic solvents instead of vegetable oils. For instance, example 1 of Butler et al. uses ethanol, ethyl, acetate, acetonitrile, isopropynol, methanol, and the like. Likewise, example 2 through example 10 of Butler et al. show azadirachtin containing neem seed extract in an aromatic petroleum distillate. In other words, none of the examples in Butler et al. illustrate the use of azadirachtin, at least one vegetable oil, and at least one surfactant wherein the formulation is storage stable and contains substantially no water. The advantages of not using organic solvents are illustrated at page 7, lines 31-33 of the present application.

As for independent claim 14, claim 14 also recites that substantially no water is present. Therefore, for the same reasons set forth above, with respect to claim 1, claim 14 should also be allowable:

At page 3 of the final Office Action, the Examiner rejects claims 1-3, 5, 14, 17, and 19 under 35 U.S.C. §102(b) as being anticipated by Kleeberg (EP 0 579 624). The Examiner essentially relies on the reasons set forth in the first Office Action. More specifically, the Examiner asserts that claim 1 of Kleeberg shows the present invention, and that dilution is shown in claims 10 and 17 of Kleeberg. For the following reasons, this rejection is respectfully traversed.

Kleeberg is substantially different from the claimed invention in several ways. First, Kleeberg does not teach or suggest the use of a vegetable oil, such as sesame oil, as in the claimed invention. In fact, claim 9 of Kleeberg suggests using organic solvents such as ketones,

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alcohols (such as 1-butanol, pentanol), esters (such as acetic ethyl ester, acetic acid n-butyl ester) or halogenated hydrocarbons (such as dichloromethane, trichloromethane). Second, the material in Kleeberg is a powdery concentrate as suggested in claim 13 of Kleeberg. Additionally, unlike the claimed invention, the actual storage life of the material is not specified. As for the materials stored in the surfactant, it can only be stored for several months. Therefore, Kleeberg does not show a “storage stable” pesticide formulation, as that term is used in the claimed invention.

With regard to claims 10 and 17 of Kleeberg, claim 10 refers to the ratios of solvent to water being 1:10 in the previous claims, and claim 17 refers to the case in which the azadirachtin-rich surfactant phase is diluted with water in a specified ratio. Both of these claims appear to refer to a step in the process of producing the product of claim 1 in Kleeberg. Claim 1 of Kleeberg recites the extraction step used to remove organic compounds from the raw plant material. Claims 10 and 17 do not recite a subsequent step involving the production of a multi-component pesticide formulation with the compounds specified in the claims, or the application of such a formulation to plant life. Therefore, these claims do not seem pertinent to the claimed invention. Accordingly, in light of all of the above, this rejection should be withdrawn.

At page 3 of the final Office Action, the Examiner rejects claims 1-7, 14-17, and 19 under 35 U.S.C. §102(b) as being anticipated by the Dimetry et al. article published in 1997. The Examiner relies on the reasons set forth in the first Office Action. The Examiner asserts that Dimetry et al. shows an azadirachtin compound with a surfactant and sesame oil at designated percentages and dilution with water. For the following reasons, this rejection is respectfully traversed.

As recited in claims 1, 3, and 14, the claimed invention relates to a pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin or at least one neem extract, wherein the formulation contains substantially no water. The Dimetry et al. formulation and the claimed invention differ on grounds that Dimetry et al. only shows a formulation with water, as can be seen from column 1 at page 396. However, the claimed invention as recited in claims 1, 3, and 14 contains substantially no water. As stated earlier, the lack of water is an important feature of the claimed invention, since the presence of water is known to degrade azadirachtin, as is set forth at page 5, lines 19-23 of the application and as set forth in the attached Declaration from one of the inventors, namely, Dr. M. C. Gopinathan.

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Additionally, Dimetry et al. does not teach or suggest the use of a formulation as storage stable azadirachtin, which is recited in the claims. The formulation of Dimetry et al. is not storage stable because its formulation contains water, and, as previously noted, azadirachtin is unstable in the presence of water and other solvents. To further show this point, one of the inventors conducted comparative experiments to compare the present invention with Dimetry et al. As shown in the attached Declaration submitted under 37 CFR §1.132, the formulation of Dimetry et al. which contained water along with small amounts of sesame oil and a surfactant had a very low storage stability. In other words, the storage stability was poor compared to the present invention which contained substantially no water. Thus, clearly Dimetry et al. is not a storage stable product and is different, for the reasons stated above, from the claimed invention. Accordingly, in light of all of the above, this rejection should be withdrawn.

Also at page 3 of the final Office Action, the Examiner rejects claims 1-5, 14, 15, 17, and 19 under 35 U.S.C. §102(b) as being anticipated by the 1983 article by Schauer. The Examiner again relies on the reasons set forth in the first Office Action. The Examiner asserts that Schauer shows a neem seed extract with synergistic sesame oil, lecithins, surfactant, and glycerol, and shows a formulation having insecticide properties, as recited at page 143 of the cited reference. For the following reasons, this rejection is respectfully traversed.

As explained earlier, independent claims 1, 3, and 14 all require the presence of substantially no water in the pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin. Therefore, there is a significant difference between the cited reference and the claimed invention. As set forth at page 142 of Schauer, the formulation is prepared by dissolving a tertiary-methyl-butyl ether extract (“MTB”) in methanol and further diluted with distilled water, and then adding aqueous solution and various additives, such as glycerol, sesame oil, and two different lecithins. Schauer et al. teaches diluting the MTB extract with water prior to addition of sesame oil. Furthermore, Schauer et al. only teaches the use of an MTB extract as a neem seed; however, it does not teach or suggest that azadirachtin would be a significant component. In fact, Schauer et al. does not even mention azadirachtin.

Because the formulation used in Schauer contains large amounts of water, it does not have any improved storage stability. As such, the cited article does not recite improved storage stability, which is a feature recited in the claims of the present invention.

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Moreover, the use of lecithin further degrades active ingredients due to its ionic properties. Certain claims of the present application recite non-ionic surfactants.

Accordingly, in light of the above, this rejection should be withdrawn.

Also at page 3 of the Office Action, the Examiner rejects claims 1-12, 14-19, 23, and 24 under 35 U.S.C. §103(a) as being unpatentable over Larson (U.S. Patent No. 4,556,562) in view of Kleeberg, Dimetry, and Ujihara (U.S. Patent No. 6,034,128). The Examiner essentially relies on the same reasons set forth in the first Office Action. The Examiner asserts that Larson shows a storage stable azadirachtin containing surfactant, neem oil, and substantially no water or solvent, that is stable for up to two years. The Examiner concludes that it would have been obvious for a person of ordinary skill in the art to use Larson's composition with A and B constituents shown by Kleeberg, and with the adjuvant shown by Dimetry, to produce the claimed invention. For the following reasons, this rejection is respectfully traversed.

As stated earlier in the November 20, 2001 response to an Office Action, the significance of Ujihara reference to the present rejection is unclear because the Examiner does not specifically explain the relevance of this reference in the rejection, as it is not apparent from the examination of the reference itself. In the present final Office Action, the Examiner still did not clarify the significance of this reference. As stated previously, Ujihara relates to a compound used as an insecticide, but it does not seem to relate to azadirachtin or a component of neem seed oil. Additionally in the November 20, 2001 response to an Office Action, the applicants requested the Examiner to clarify the significance of the Kleeberg reference, since the two forms of azadirachtin do not appear to be directly mentioned in Kleeberg reference as recited in claim 8 of the present application. As such, the applicants can only conclude that the Kleeberg reference is not material to this rejection.

Further, Larson relates to a method of extracting various active ingredients from neem seed, diluting the resultant extract to form an aqueous emulsion, and then adjusting its pH to a specific range. Larson specifically mentions the use of water. The presence of water as a diluent in Larson is shown at column 3, lines 53-63 and in claim 1. As such, the cited reference does not teach or suggest forming a storage stable pesticide concentrate that contains substantially no water. The formulation of Larson clearly includes water, which is different from the claims of the present application. Therefore, Larson does not teach or suggest the claimed invention. Furthermore, one skilled in the art would not have a reason to look at any other publication in

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view of Larson, since Larson already provides a method to achieve storage stability. Therefore, one of ordinary skill in the art would not seek to combine the teachings of Larson with any other reference to solve the stability problem, since Larson already provides a solution for that problem.

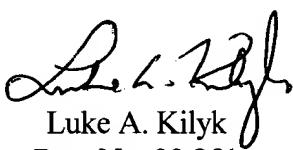
As stated previously, like Larson, Dimetry et al. forms a formulation using water with sesame oil. Since both Dimetry et al. and Larson have a formulation formed with water, one skilled in the art by reading Larson in view of Dimetry et al. would formulate a composition having water. Moreover, the sesame oil used in Dimetry et al. is below one weight percent, which is quite different from the amounts recited in claims 10, 23, and 24 of the present application. None of the references or combination thereof shows the presence of vegetable oil in the substantial absence of water. The Examiner has not explained why one skilled in the art would assume that the addition of an oil in Larson or Kleeberg would not affect the long-term stability of the emulsion, nor has the Examiner explained why one skilled in the art would believe that sesame oil would be stable in the presence of solution described by Larson. Accordingly, in light of the above, this rejection should be withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request the reconsideration of this application and the timely allowance of the pending claims.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Twice Amended) A pesticide formulation comprising at least one vegetable oil, at least one surfactant, and azadirachtin, [wherein said formulation is storage stable and] wherein said formulation contains [substantially no water] less than about 2% by weight water, based on the weight of the formulation.
2. (Amended) A pesticide formulation comprising at least one vegetable oil, at least one non-ionic surfactant, and azadirachtin, wherein said formulation is storage stable and contains [substantially no water] less than about 2% by weight water, based on the weight of the formulation, wherein said formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after 1 year of storage at 25°C in a sealed container.
3. (Twice Amended) A storage stable pesticide formulation comprising at least one vegetable oil, at least one non-ionic surfactant, and a neem seed extract, wherein said neem seed extract comprises azadirachtin, and wherein said formulation contains [substantially no water] less than about 1/2% by weight water, based on the weight of the formulation, wherein said formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after 1 year of storage at 25°C in a sealed container.
9. (Amended) The formulation of claim [3] 1, wherein said formulation is storage stable such that at least 90% by weight of the azadirachtin originally present remains after 1 year of storage at 25°C in a sealed container.
14. (Twice Amended) A storage stable pesticide formulation formed by mixing at least one vegetable oil, at least one non-ionic surfactant, and at least one neem extract together to form said formulation, wherein said neem extract comprises at least azadirachtin, and wherein said formulation contains [substantially no water] less than about 2% by weight water, based on the weight of the formulation.

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Date April 30, 2002 Label No. EV074199411US

I hereby certify that, on the date indicated above, I deposited this paper with identified attachments and/or fee with the U.S. Postal Service and that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

Dawn M. Berry
Name (Print)

Dawn M. Berry
Signature

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

DAMARLA, et al.

Application Number: 09/536,351

Filed: March 27, 2000

) Art Unit: 1616

) Examiner: Levy N.

For: STORAGE STABLE PESTICIDE FORMULATIONS CONTAINING AZADIRACHTIN

DECLARATION UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, DC 20231

April 30, 2002

Sir:

I, Dr. M.C. Gopinathan do declare and state as follows:

- 1.) I am one of the named inventors of the above-identified U.S. patent application.
- 2.) I am also the Manager of Research and Development for E.I.D. Parry (India) Limited, who is the assignee of the present application. I have been employed by E.I.D. Parry (India) Limited for about 13 years.
- 3.) I am responsible for the research and development of products containing azadirachtin, and I am very familiar with the materials described and claimed in the present application. The examples set forth in the present application were prepared under my direct supervision.

Declaration Under 37 C.F.R. §1.132
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- 4.) I am very familiar with the present application and the communications received from the U.S. Patent & Trademark Office, including the Office Action dated February 5, 2002.
- 5.) This Declaration is submitted so that the Examiner can appreciate that the following experiments demonstrate the differences and unexpected superiority of the claimed invention over the cited references.
- 6.) Pesticide compositions containing neem seed extract (e.g., azadirachtin) and sesame oil were prepared under my direct supervision in the same manner as in the Examples of the present application. These compositions were tested to confirm that the sesame oil provides stability to azadirachtin in neem seed extracts, and that if any substantial water is present in the sesame oil composition, the water causes rapid degradation to azadirachtin.
- 7.) In more detail, the following test results illustrate that azadirachtin in sesame oil remains stable compared to azadirachtin containing water. This indicates that sesame oil provides stability to azadirachtin in neem seed extracts and that water, if present in the sesame oil composition, causes rapid degradation to azadirachtin.

Experiment 1

Stability of Azadirachtin in the formulation of Dimetry et al.

Objective : To demonstrate the higher stability of the formulation of the present invention compared to the Dimetry formulation.

To one part of the composition of the present invention, 10 parts of 0.6% of sesame oil (emulsified with 0.01% Tween 85) is added and mixed thoroughly to form a uniform suspension. The formulation was taken in a sealed flask and evaluated with respect to the stability of Azadirachtin under accelerated conditions, 54 Deg C. Rapid degradation of Azadirachtin (87.59%) was observed in the formulation compared to the formulation of the present invention (18.63%)

Sl.No.	Composition	Initial Aza	(%) Drop at 54 Deg C in 7 days
1	Azadirachtin extract + Tween 85 + Sesame oil (Composition of the present invention)	1.02	18.63
2	Dimetry formulation* (Composition of the present invention +0.6% sesame oil emulsified with 0.01% Tween 85, 1:10)	0.09*	87.59

*Dimetry et al. used a formulation containing 1.0% Azadirachtin and mixed 0.6% of sesame oil emulsified with 0.01% Tween. Hence Dimetry's composition contains around 0.09% Azadirachtin only, whereas the Azadirachtin content of present invention is 1.0%.

Result: The stability of Azadirachtin in the Dimetry formulation is far lower than the stability of Azadirachtin in the formulation of the present invention. It also demonstrates that the Dimetry et al. formulation is a ready to use formulation and is not a storage stable one.

As can be seen, the formulation of Dimetry et al. is not storage stable and is quite different from the storage stability of the present application as shown in the above experiment. Clearly, the use of small amounts of sesame oil along with water does not provide any storage stability, which is quite different from the claimed invention. In my opinion, Dimetry et al. clearly does not teach the present invention.

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Experiment 2

The following two compositions were prepared to evaluate the stabilizing effect of sesame oil on azadirachtin and the effect of water on the stability of azadirachtin in sesame oil.

- (i) *Composition of neem seed extract (azadirachtin) and sesame oil:* A saturated solution of the neem extract containing azadirachtin in sesame oil, used in the present invention, was prepared. The azadirachtin content of the composition was 0.9%. The stability of azadirachtin in this composition was evaluated at 54°C for 28 days.
- (ii) *Composition of sesame oil containing neem seed extract + Water:* Composition (i) was treated with 10% Tween 85 in water (20:1), mixed thoroughly and the stability evaluated.

Sl.No.	Composition	Initial Azadirachtin	(%) Drop at 54°C in 28 days
1	Azadirachtin + Sesame oil (Mixed thoroughly and centrifuged to obtain clear solution)	0.11	11.8%
2	Sesame oil containing Azadirachtin + 10% Tween 85 in water(20:1)	0.10	64.0%

Conclusion

Azadirachtin in sesame oil remains stable (only 11.00% drop in 28 days at 54°C) compared to that containing water (64.0% drop in 28 days at 54°C). This indicates that sesame oil provides stability to azadirachtin in neem seed extracts, and that water present in sesame oil compositions causes rapid degradation to azadirachtin.

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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and any such willful false statement may jeopardize the validity of the application or any issuing thereon.

Dr. M.C. Gopinathan, General Manager (R& D)
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Date : April 30, 2002

